

**“A STUDY TO KNOW THE EFFECT OF EXERCISE CAPACITY
IN COPD PATIENTS BY USING HIGH INTENSITY TREADMILL
TRAINING AND LOW INTENSITY TREADMILL TRAINING”.**

A Dissertation Submitted To

**THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY
CHENNAI**

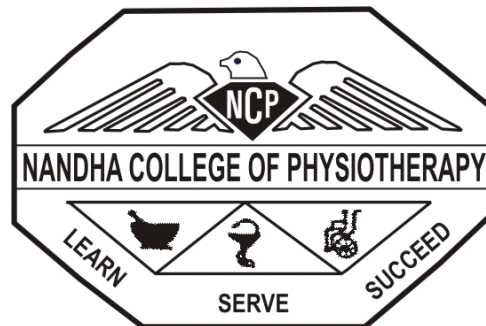
In partial fulfillment of the requirements for the awards of the

MASTER OF PHYSIOTHERAPY DEGREE

(Physiotherapy in Cardio - Respiratory)

Submitted by

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NANDHA COLLEGE OF PHYSIOTHERAPY

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APRIL- 2017

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Under the guidance of

Prof. R.SARAVANAKUMAR., M.P.T (Cardio)

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Place : Erode

Guide Signature

Date :

DECLARATION

I hereby and present my project work entitled “**A STUDY TO KNOW THE EFFECT OF EXERCISE CAPACITY IN COPD PATIENTS BY USING HIGH INTENSITY TREADMILL TRAINING AND LOW INTENSITY TREADMILL TRAINING**”. is outcome of original research work is undertaken and carried out by me under the guidance of **Prof. R.SARAVANAKUMAR., M.P.T (Cardio)** To the best of my knowledge this dissertation has not been formed in any other basic for the award of any other degree, diploma, associateship, fellowship, previously from any other medical university.

Reg.No. 271530081

ACKNOWLEDGEMENT

I am very happy to express my heartfelt thanks to the **GOD** almighty for giving me strength and wisdom in successfully completing this project work in an efficient manner.

I would like to pay my gratitude to my **Family** members who always had so much confidence in me and always provided me with a constant silent support, encouragement and inspiration.

I express my sincere Gratitude to our **Principal, Prof. V.MANIVANNAN, M.P.T., (Ortho)., Nandha college of Physiotherapy, Erode** for leading me to this success.

I am very much happy to express my heartfelt thanks to my guide to **Prof. R.SARAVANAKUMAR., M.P.T (Cardio)** for his valuable support for completing this project successfully.

I also express my gratitude to the beloved **staffs of Nandha College of Physiotherapy** for leading me to this success.

Last but not least, I also have much gratitude to my **FRIENDS** for their known interest and in my academic excellence.

PREFACE

It was an immense pleasure for me to present this project work on “**A STUDY TO KNOW THE EFFECT OF EXERCISE CAPACITY IN COPD PATIENTS BY USING HIGH INTENSITY TREADMILL TRAINING AND LOW INTENSITY TREADMILL TRAINING**”. because this opportunity made me to learn a lot about this condition. I have done this work with my best level by referring many cardio- thoracic clinical, rehabilitation books, exercise therapy books, journals and websites. I have assessed and given treatment to patient to improve their condition. I believe this project work will prove to be very useful for the physiotherapists to give a better knowledge while assessing and treating COPD patients.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a lung disease that includes chronic bronchitis and emphysema. 5% of global population are suffered by this disease.

In 80-90% of cases, it is caused by smoking, pollution in developing countries and aging and the genetic reasons are for developed countries.

In chronic bronchitis, the airways become swollen and can be filled with mucus, which can make it hard to breathe.

In emphysema, the air sacs (alveoli) in the lungs are damaged which can make it hard to breathe

COPD develops over time. In most cases, COPD is diagnosed in people over 40 years of age. Someone with COPD may not realize that they are becoming more shortness of breath until it becomes very hard to do simple tasks like walking up stairs. In COPD, the lungs are obstructed or blocked, making it hard to breathe.

There are treatments to help breathe more easily, but they can't reverse the damage caused – so it's important to get an early diagnosis.

COPD may need to be differentiated from other causes of shortness of breath such as congestive heart failure, Pulmonary embolism, Pneumonia, or pneumothorax. Many people with COPD mistakenly think they have asthma. The distinction between asthma and COPD is made on the basis of the symptoms, smoking history, and whether airflow limitation is reversible with bronchodilators at spirometry.

Most cases of COPD are potentially preventable through decreasing exposure to smoke and improving air quality. Annual influenza vaccinations in those with COPD reduce exacerbations, hospitalizations and death.

Pulmonary rehabilitation is a program of exercise, disease management and counseling, coordinated to benefit the individual.¹ In those who have had a recent exacerbation, pulmonary rehabilitation appears to improve the overall quality of life and the ability to exercise. Pulmonary rehabilitation has been shown to improve the sense of control a person has over their disease, as well as their emotions.

Performing endurance exercises improves body movement for people with COPD, and may result in a small improvement in breathlessness. Breathing exercises in and of themselves appear to have a limited role. Pursed lip breathing exercises may be useful. Treadmill, cross trainer, static cycling exercises appear to be safe to practice for people with COPD, and may be beneficial for pulmonary function and pulmonary capacity when compared to a regular treatment program.

1.1 OPERATIONAL DEFINITIONS

1.1(a) COPD:

COPD is the disease characterized by presence of airflow obstruction due to chronic bronchitis or emphysema; the airflow obstruction due to chronic bronchitis or emphysema the airflow obstruction is generally progressive may be accompanied by airway reactivity and may be partially reversible.

American thoracic society

1.1(b) TREADMILL:

Treadmill is a motorized or manual machine with a movable platform to walk on it.

1.1(c) PULMONARY FUNCTION TEST:

Pulmonary function test is a group of tests (FVC,FEV₁and PEFR) that measure how well the lungs take in and release air.

1.2 NEED FOR STUDY:

In COPD, the pulmonary function test is not a diagnostic one, but it can determine the airflow limitation. The spirometry is used to take the pulmonary function test values. This is typically based on the FEV₁ expressed as a percentage of the predicted "normal" for the person's age, gender, height and weight. Both the American and European guidelines recommended partly based treatment recommendations on the FEV₁

The GOLD guidelines suggest dividing people into four categories based on symptoms assessment, airflow limitation,weight loss, muscle weakness and as well as the presence of other diseases, should also be taken into account.

So we give the high and low intensity treadmill training for the COPD patients and take the pre and post value of the pulmonary function test.

Peak flow readings are higher when patients are well, and lower when the airways are constricted. From changes in recorded values, patients and doctors may determine lung functionality, the severity of COPD symptoms, and treatment. So we use PEFR also with the FVC and FEV₁.

1.3 AIM OF THE STUDY

The aim of the study is to know the Breathing capacity in COPD patients by using high intensity treadmill training and low intensity treadmill training.

1.4 OBJECTIVE OF THE STUDY

- To determine the effect of high intensity treadmill training on exercise capacity in COPD subjects while measuring pulmonary function test.
- To determine the effect of low intensity treadmill training on exercise capacity in COPD patients while measuring pulmonary function test.
- To compare the effect of breathing capacity in COPD patients by using high intensity treadmill training and low intensity treadmill training.
- To find out the effective training to improve the exercise capacity for COPD patients.

1.5 HYPOTHESIS

1.5(a) NULL HYPOTHESIS

The null hypothesis states that there is no significant difference between high intensity treadmill training and low intensity treadmill training on exercise capacity in COPD patients.

1.5(b) ALTERNATE HYPOTHESIS

The alternate hypothesis state that is a significant difference between high intensity treadmill training and low intensity treadmill training on exercise capacity in COPD patients.

1.6 ASSUMPTION

The study has been conducted assuming that high intensity treadmill training is effective than low intensity treadmill training on COPD patient's exercise capacity.

1.7 PROJECTED OUTCOME

Based on the Review of literature, the outcome of my study will be that the High intensity treadmill training is effective than low intensity treadmill training in COPD patient's exercise capacity.

REVIEW OF LITERATURE

- 1) **Eriksson G, Jarenbäck L, Peterson S, Ankerst J, Bjerner , Tufvesson E.(2014)** Continuous analyses of different lung function parameters over the spirometric COPD severity range gave valuable information additional to categorical analysis. Parameters related to volume, diffusion capacity, and reactance showed break-points around 65% of FEV1, indicating that air trapping starts to dominate in moderate COPD (FEV1 =50%-80%). This may have an impact on the patient's management plan and selection of patients and/or outcomes in clinical research
- 2) **Borel B, Provencher S, Saey D, Maltais F(2013)** states that Exercise intolerance is a key element in the pathophysiology and course of Chronic Obstructive Pulmonary Disease (COPD). As such, evaluating exercise tolerance has become an important part of the management of COPD. A wide variety of exercise-testing protocols is currently available, each protocol having its own strength and weaknesses relative to their discriminative, methodological, and evaluative characteristics.
- 3) **Hsia D, Casaburi R, Pradhan A, Torres E, Porszasz J(2009)** conducted the study that Physiological responses to linear treadmill and cycle ergometer exercise in COPD and which one is efficient to the pulmonary rehabilitation. The result of the study concluded that the bruce protocol is one of the tool for standardized one for monitoring
- 4) **Laviolette L, Bourbeau J, Bernard S, Lacasse Y, Pepin V, Breton MJ, Baltzan M, Rouleau M, Maltais F(2008)** reported that The cycle endurance test was more responsive than the 6-minute walking test, in detecting improvement in exercise tolerance following pulmonary

rehabilitation, and was also better correlated with improvements in health status.

- 5) **Wen H, Gao Y, An JY(2008)** did the comparison to two training programs in rehabilitation for patients with moderate to severe chronic obstructive pulmonary disease (COPD). Both the High intensity and the control groups had significant improvements in exercise capacity and dyspnea after pulmonary rehabilitation. The degree of improvement in both groups was similar. But the high intensity group showed significant improvement in the anaerobic threshold and decrease in ventilatory requirement.
- 6) **McKeough ZJ¹, Alison JA, Speers BA, Bye PT(2008)** suggests that an intensity of 80% peak work rate may be too high as an initial training intensity for supported arm exercise in people with COPD
- 7) **Pepin V, Saey D, Laviolette L, Maltais F(2007)** states that the Patients with chronic obstructive pulmonary disease (COPD) are often caught in a downward spiral that progresses from expiratory flow limitation to poor quality of life and invalidity. Within this downward spiral, exercise tolerance represents a key intermediate outcome. As recently stated by the GOLD initiative, improvement in exercise tolerance is now recognized as an important goal of COPD treatment.
- 8) **Butcher SJ, Jones RL(2006)** reported that the impact of exercise training intensity on change in physiological function in patients with chronic obstructive pulmonary disease. Higher intensity training elicits greater physiological change than lower intensity training; however, there is no consensus as the exercise training intensity that elicits the greatest physiological benefit while remaining tolerable to patients.

- 9) **Franssen FM, Broekhuizen R, Janssen PP, Wouters EF, Schols AM(2004)** did the Effects of whole-body exercise training on body composition and functional capacity in normal-weight patients with COPD and concluded that intensive exercise training per session is able to induce an anabolic response in normal-weight patients with COPD classified into Global Initiative for Chronic Obstructive Lung Disease stages III-IV. Improvements in exercise performance and muscle function are proportionally larger than increases in Fat free mass(FFM).
- 10) **Mador MJ, Bozkanat E, Aggarwal A, Shaffer M, Kufel TJ(2004)**Conducted the study to compare the effects of endurance training only to endurance plus strength (combined) training in a randomized trial of patients with COPD and got the result was Strength training can lead to significant improvement in muscle strength in elderly patients with COPD. However, this improvement in muscle strength does not translate into additional improvement in quality of life, exercise performance or quadriceps fatigability compared to that achieved by endurance exercise alone.
- 11) **Collins EG, Fehr L, Bammert C, O'Connell S, Laghi F, Hanson K, Hagarty E, Langbein WE(2003)** study was to evaluate the efficacy of an unique program of ventilation-feedback training combined with leg-cycle exercise to improve exertional endurance and decrease perceived dyspnea in patients with chronic obstructive pulmonary disease (COPD).
- 12) **Rochester CL(2003)**concluded that Exercise training in a pulmonary Rehabilitation programme (PRP) improved submaximal exercise capacity. Only patients who completed high-intensity exercise training

showed improvements in maximal exercise capacity, FVC and work efficiency.

- 13) **Hawkins PJ, Johnson LC, Nikolettou DH, Hamnegård CH, Sherwood R, Polkey MI, Moxham (2002)** concluded that pulmonary assisted ventilation (PAV) enables a higher intensity of training in patients with severe COPD, leading to greater improvements in maximum exercise capacity with evidence of true physiological adaptation
- 14) **Cooper CB (2001)** states that endurance exercise training (EXT) is singly the most important aspect of rehabilitation for patients with chronic pulmonary disease. When effective, this modality of physical reconditioning leads to improved functional exercise capacity and reduced breathlessness. Early implementation is desirable to obtain more meaningful responses (e.g., when FEV1 falls below 50% of the predicted value in patients with chronic obstructive disease).
- 15) **Covey, et.al., (2001)** conducted a comparative study to indicate the effect of high intensity vs low intensity training on 50 patients through Borg scale and 6 minute walk test, the high intensity treadmill training by bruce protocol with 80% THR and low intensity treadmill training by cooper protocol training with 60% THR was given regularly. The result of study marked improvement in tolerance and reduction in dyspnea on exertion following high intensity compared to low intensity training.
- 16) **Bourjeily G, Rochester CL (2000)**, states that ventilatory muscle training should be considered for patients who continue to experience exercise limitation and breathlessness despite medical therapy and general exercise reconditioning. Exercise tolerance may improve following exercise training because of gains in aerobic fitness or peripheral muscle strength; enhanced mechanical skill and efficiency of exercise; improvements in respiratory muscle function, breathing

pattern, or lung hyperinflation; as well as reduction in anxiety, fear, and dyspnea associated with exercise.

- 17) **James E.et.al.,(1999)** conducted an experimental study to find out the reliability of six minute walk test for COPD patients. The patients are formed to three groups. One group was tested with ergometry, the others are bicycle test and walking test.

MATERIALS AND METHODOLOGY

3.1 MATERIALS

- Computerised spirometer and its accessories
- Mouth pieces
- Peak flow meter.
- Treadmill unit and its accessories
- Couch, stool and pillows
- Sphygmomanometer
- Stethoscope

3.2 METHODOLOGY

- All patients underwent cardiopulmonary examination and postural evaluation.
- Bruce protocols and Modified Bruce protocol is conducted to confirm the diagnosis.

3.3 STUDY DESIGN

The design that is used for this study is the Quasi Experimental design.

- Pre and Post Experimental design.

3.4 POPULATION

30 Patients with age group of 30 to 60 years having COPD.

3.5 STUDY SETTING

- Outpatient Department - Nandha College of physiotherapy, Erode
- Dhanvanthiri Critical Care, Erode.
- Sudha Multi Speciality Hospital, Erode

3.6 STUDY DURATION

- Study was conducted for a period of 9 months.

3.7 TREATMENT DURATION

- 18 minutes per day, 3 days in a week for 3 months.

3.8 STUDY SAMPLING

- Convenient sampling method.

3.9 SAMPLE SIZE

- A total of 30 COPD patients:
 - Group A [high intensity training group – 15 subjects]
 - Group B [low intensity training group – 15 subjects]

3.10 CRITERIA FOR SAMPLE SELECTION

3.10(a) INCLUSION CRITERIA

- Age: 30 to 60 years
- Sex : both male and female
- Stable clinical functional status
- The COPD patients able to walk in treadmill with FEV1 more than 60%.

3.10(b) EXCLUSION CRITERIA

- Poor compliance
- Neurological disorder
- Severe chest wall deformities
- Cardiac abnormalities
- Uncontrolled hypertension
- Rheumatoid arthritis
- Severe osteoporotic patients
- DVT
- Renal dysfunction and diseases

3.11 PARAMETER

Pulmonary Function Test (PFT)

3.12 VARIABLES OF THE STUDY

FVC - Forced Vital Capacity

FEV1 - Forced Expiratory Volume in one second

PEFR - Peak Expiratory Flow Rate

3.13 PROCEDURE

30 COPD subjects were involved in this study according to inclusion and exclusion criteria, 15 in each group.

A pre-test is conducted for group A and Group B on pulmonary function test.

After a brief demonstration about high intensity treadmill training Group A subjects were subjected to high intensity treadmill training for a period of 12 weeks with a frequency of 3 sessions / week.

After a brief demonstration about low intensity treadmill training Group A subjects were subjected to low intensity treadmill training for a period of 12 weeks with a frequency of 3 sessions / week.

Post- test is conducted for group A and Group B by pulmonary function test for exercise capacity and finally the pre and post tests values were computed and analyzed.

DATA PRESENTATION AND ANALYSIS

STATISTICAL TOOLS

For the pre and post test experimental study, both paired and unpaired 't' test are used for each parameter in an intra group analysis to find out the significance of improvement achieved through intervention. Then unpaired 't' test was used to find out the significance of the changes between two groups i.e., inter-group analysis.

PAIRED 't'-TEST

To compare the effect between two groups 't' test for paired values.

Formula for paired t-test

$$S = \frac{\sum d^2 - \frac{(\sum d)^2}{n}}{n-1}$$

$$t = \frac{\bar{d}\sqrt{n}}{s}$$

d = difference between the pre test and post test

\bar{d} = Mean difference

n = Total number of subjects

S = Standard deviation

UNPAIRED t- TEST

The unpaired t-test is used to compare the effects between two groups, 't' test for unpaired values

Formula unpaired t –test

$$S = \sqrt{\frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{n_1+n_2-2}}$$

$$t = \frac{|\bar{x}_1 - \bar{x}_2|}{s \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

n_1 = Total number of patients in Experimental Group

n_2 = Total number of patients in Control Group

\bar{X}_1 = Mean difference between pre test and post test of Experimental Group

\bar{X}_2 = Mean difference between pre test and post test of Control Group

S_1 = Difference between pre test and post test of Experimental Group

S_2 = Difference between pre test and post test of Control Group

TABLE-4.1

COMPARISON OF VARIABLES

MEAN DIFFERENCE BETWEEN GROUP A AND GROUP B

VARIABLES	GROUP A	GROUP B
FVC	83	77
FEV1	80	77
PEFR	209	197

FIGURE-4.1

MEAN DIFFERENCE BETWEEN

GROUP A AND GROUP B

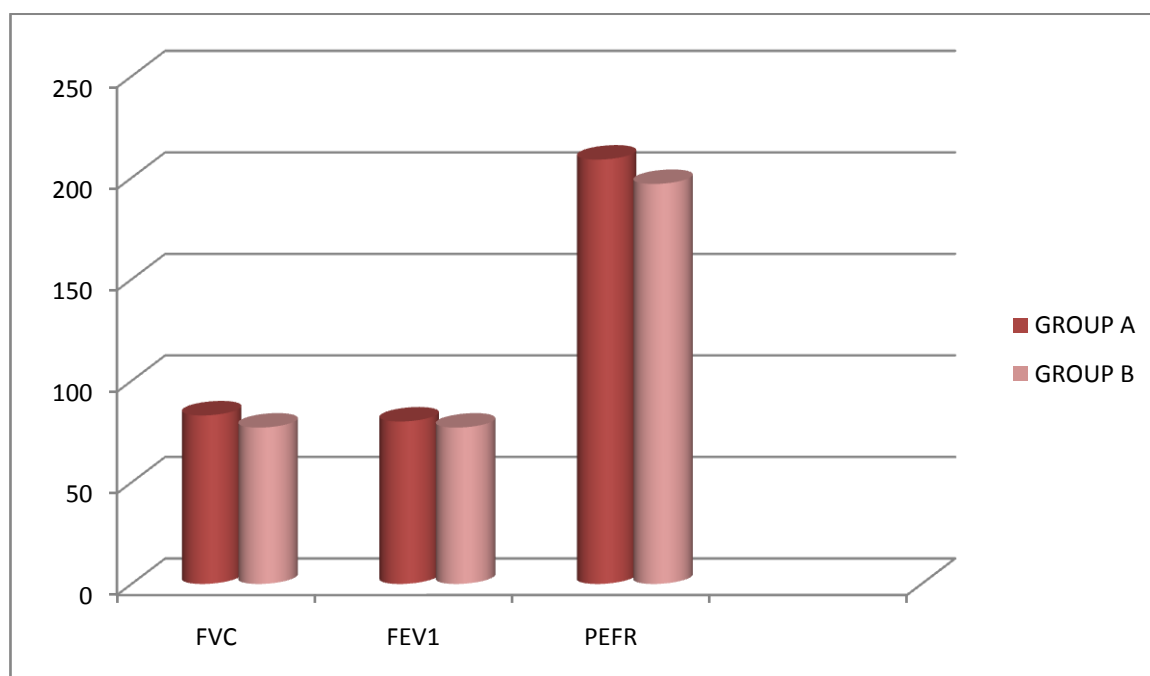


TABLE-4.2
COMPARISON OF VARIABLES
STANDARD DEVIATION BETWEEN GROUP A AND GROUP B

VARIABLES	GROUP A	GROUP B
FVC	1.26	1.06
FEV1	2.93	1.69
PEFR	3.51	3.13

FIGURE-4.2
STANDARD DEVIATION BETWEEN GROUP A AND GROUP B

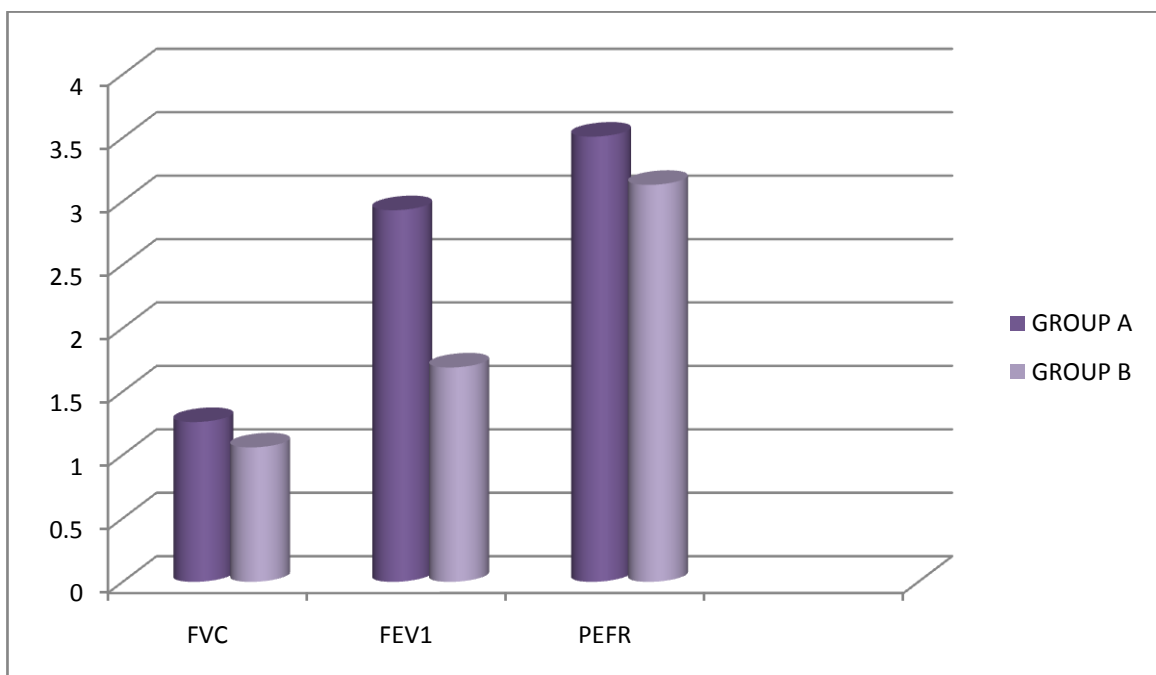


TABLE-4.3
COMPARISION OF THE PAIRED 't' TEST VALUE BETWEEN
GROUP A AND GROUP B

GROUPS	CALCULATED 't'VALUE		TABLE VALUE	SIGNIFICANCE
	GROUP A	GROUP B		
FVC	250.31	175.20	2.15	SIGNIFICANT
FEV1	103.75	102.30	2.15	SIGNIFICANT
PEFR	226.26	196.85	2.15	SIGNIFICANT

FIGURE-4.3
COMPARISION OF THE PAIRED 't' TEST VALUE BETWEEN
GROUP A AND GROUP B

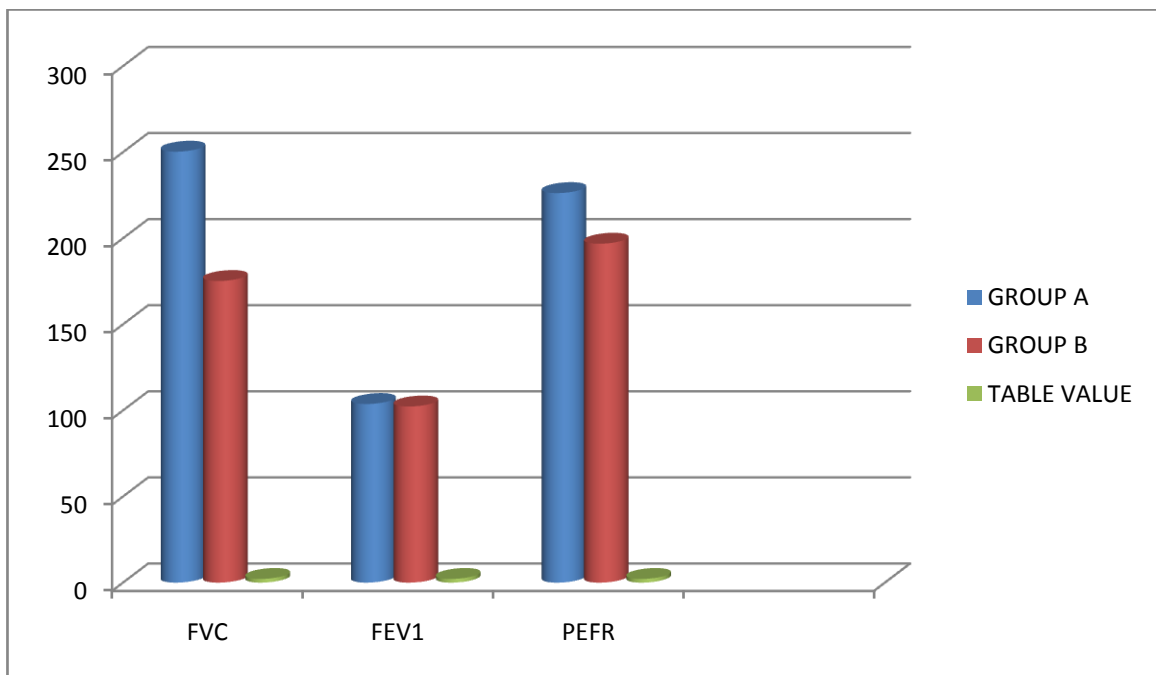
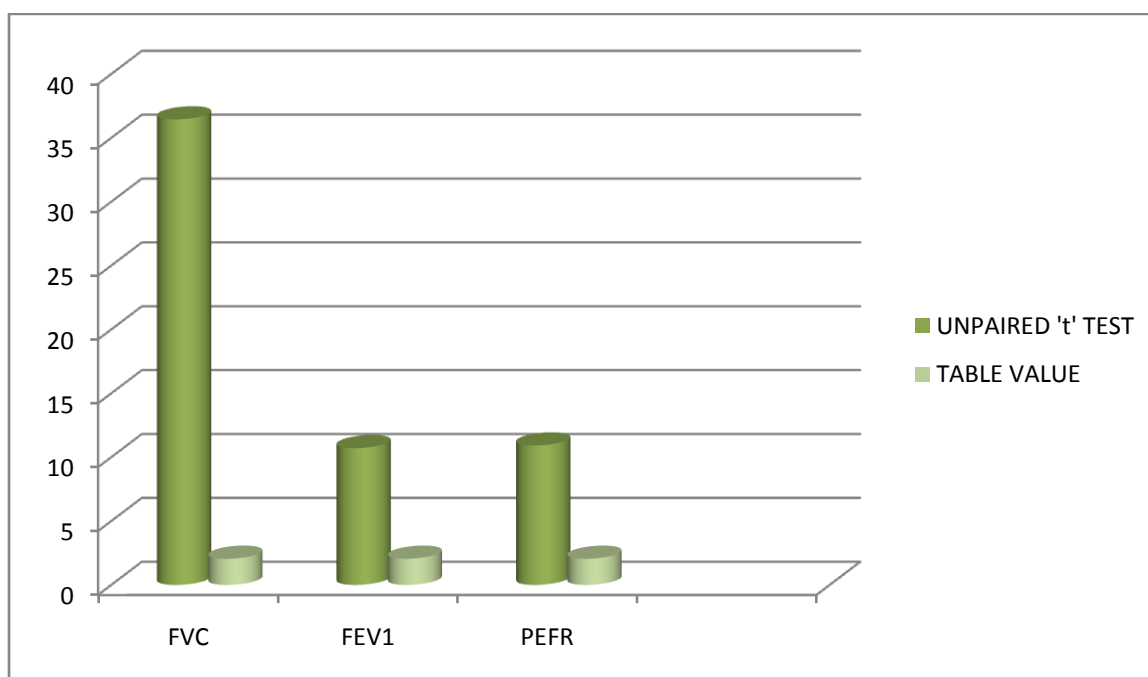


TABLE-4.4
COMPARISION OF UNPAIRED 't' TEST AND TABLE VALUE
BETWEEN PFT

VARIABLES	UNPAIRED 't' TEST	TABLE VALUE	SIGNIFICANCE
FVC	36.45	2.05	SIGNIFICANT
FEVI	10.71	2.05	SIGNIFICANT
PEFR	10.92	2.05	SIGNIFICANT

FIGURE- 4.4
COMPARISION OF UNPAIRED 't' TEST AND TABLE VALUE
BETWEEN PFT



RESULTS AND DISCUSSION

5.1 RESULTS

The study sample comprised 30 patients, of which 15 were experimental group and 15 were control group. The mean age of patients is 56 years. Among 30 patients, 15 were trained with high intensity treadmill training, and 15 were trained with low intensity treadmill training.

The pre and post test values were assessed by PFT in group A and group B.

The mean difference value between the Group A and Group B of FVC is 83 and 77, FEV1 is 81 and 77, PEFr is 209 and 197 .

The standard deviation value between the Group A and Group B of FVC is 1.26 and 1.06, FEV1 is 2.93 and 1.69, PEFr is 3.51 and 3.13 .

The mean difference value between the Group A and Group B of FVC is 250.31 and 175.20, FEV1 is 103.75 and 102.30, PEFr is 226.26 and 196.85 respectively.

The paired 't' test value between the Group A and Group B is more than table value 2.15 for 5% level of significance at 14 degrees of freedom.

The unpaired 't' test value of FVC is 36.45, FEV1 is 10.71, PEFr is 10.92 respectively. The calculated 't' values are more than the table value 2.05 for 5% level of significance at 28 degrees of freedom.

The paired 't' test values shows that the exercise capacity of COPD patients in high intensity treadmill training is more effective than the low intensity treadmill training.

The unpaired 't' test values also shows that there is significant difference between two groups. It shows that the effect of COPD patients exercise capacity is improving by the low intensity treadmill training.

5.2 DISCUSSION

CJ Dark L cohrane., Francesco Gighiotti., both were conducted the study that low intensity training got significant improvement in exercise tolerance and reduction of dyspnea.

Covey Margaret., conducted a comparative study to find the effect of high intensity and low intensity training in COPD patients .The study shows the marked improvement in exercise tolerance and reduce the dyspnea following high intensity training compared to low intensity training.

Spirometry may help to determine the severity of airflow limitation. This is typically based on the FEV₁ expressed as a percentage of the predicted "normal" for the person's age, gender, height and weight. Both the American and European guidelines recommended partly basing treatment recommendations on the FEV₁.

The paired 't' value between the Group A and Group B showing the effect of exercise capacity in COPD patients that high intensity treadmill training is more than the low intensity treadmill training

The unpaired 't' values shows some difference, so the low intensity treadmill training also give some improvement in exercise capacity in COPD patients. Peak flow readings are higher when patients are well, and lower when the airways are constricted. here The PEF_R also having the marked difference between the two Groups . The lung function improved by both high and low intensity treadmill training.

5.3 LIMITATIONS OF THE STUDY

- This study has been conducted on small size sample only.
- This study has taken more time to complete.
- The changes in the dependent variables are not examined at each treatment session
- Differences among groups were not identified at each session.
- Variation in calamites, drugs, diet, personal habit, gender, age could not be controlled.
- The long-term effects following the end of treatment were not investigated.

5.4 RECOMMENDATIONS

- A similar study may be extended with larger samples.
- Implement a protocol for investigating the long-term effects

SUMMARY AND CONCLUSION

From the result of this study states that the High intensity treadmill training is more effective than low intensity treadmill training for COPD patient's exercise capacity. Moreover the both high intensity treadmill training and low intensity treadmill training improve the exercise capacity and Quality of life. There was no adverse effects reported by any of the participants during the study period.

Through the results, **ALTERNATE HYPOTHESIS IS ACCEPTED** and also the study could be concluded that there is a significant difference between high intensity treadmill training and low intensity treadmill training on exercise capacity in COPD patients.

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APPENDIX-1
CARDIOPULMONARY ASSESSMENT

Name :

Age :

Sex :

Occupation :

Height : Date of Admission :

Weight : Date of assessment :

Chief complaints :

HISTORY

Present medical history :

Past medical history :

Family history :

Social History :

Personal History :

Associated problem :

Vital signs:

Heart rate :

Blood Pressure :

Respiratory rate :

Temperature :

OBJECTIVE ASSESSMENT

On observation

Built :

Color :

Chest shape :

Symmetry :

Breathing pattern :

Chest movement :

Intercostals retraction :

Periphery/extremities :

Clubbing :

Cyanosis :

Respiratory distress :

Type of respiration :

Usage of assessor muscles :

Vocal fremitus :

On Palpation

Tracheal deviation :

Chest expansion :

✓ Axilla

✓ Nipple level

✓ Xiphoid

Tenderness :

Oedema :

On Examination

On Auscultation

Heard sounds :

Lung sounds :

Abnormal breath sound :

Wheeze

Rails

Rhonchi

Crepitus

INVESTIGATION

X-Ray :

E.C.G :

Echocardiogram :

ABG Analysis :

Blood test :

Exercise tolerance :

DIAGNOSIS

TREATMENT

APPENDIX-2

ETHICAL CLEARANCE

Ethically permission for the study will be obtained from the subjects and a written consent will be taken from each subject who participates in this study, As this study involve human subjects the Ethical Clearance has been obtained from the Ethical committee of Nandha college of Physiotherapy, Erode as per the ethical guidelines for Bio-medical research on human subjects, 2000 ICMR,(Indian Council of Medical Research) New Delhi.

APPENDIX-3

Written Informed Consent Form

**NANDHA COLLEGE OF PHYSIOTHERAPY,
ERODE.**

Informed consent form for the volunteers at “Nandha college of Physiotherapy, Erode”, who will be participating in the research project entitled “**A STUDY TO KNOW THE EFFECT OF EXERCISE CAPACITY IN COPD PATIENTS BY USING HIGH INTENSITY TREADMILL TRAINING AND LOW INTENSITY TREADMILL TRAINING**”.

Name of Principal Investigator	271530081 Post graduate student
Name of Organization	Department of Physiotherapy, Nandha college of Physiotherapy, Erode

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I, _____ postgraduate student in the Department of Physiotherapy, Nandha college of Physiotherapy, Erode, am working on my dissertation titled “**A STUDY TO KNOW THE EFFECT OF EXERCISE CAPACITY IN COPD PATIENTS BY USING HIGH INTENSITY TREADMILL TRAINING AND LOW INTENSITY TREADMILL TRAINING**”.

I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them and get yourself clarified.

Purpose of the research

COPD is common disease in India and all having the continuous lung secretions, breathlessness, less exercise capacity. it should be reduce and getting to improve the ADL by improve the exercise training.

Type of Research Intervention

In this study if you are selected, detailed history taking, clinical examination and routine investigations will be done.

Participant selection

Study group: Adult between age groups of 18- 50 years presenting with history of chronic nonspecific neck pain.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. It will not affect our patient's treatment process.

Benefits

Personally you might be or may not be benefited in any way directly from the research. But by taking part in this research, you will be helping the scientific community.

Possible risks

There are no major physical risks for the person associated with these methods. Complications include exacerbation of symptoms after therapy which is rare possibility.

Reimbursements

You won't be given any monetary incentives or gifts for being a part of this research.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about the patient that will be collected during the research will be put away and no-one but the researchers will be able to see it.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact

This proposal has been reviewed and approved by the Research and Ethical committee of Nandha college of physiotherapy, Erode, which is a committee whose task it is to make sure that research participants are protected from harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have been explained the procedure and complications. I am willing to participate in the study. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Signature of Participant _____

Date _____ Day/month/year

If illiterate a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____

Thumb print of participant

Signature of witness _____

Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Blood investigations:

- Hb, TC, DC, ESR, RBS, Serum electrolytes, Blood Urea and Serum Creatinine, lung secretion collection.

2. Treadmill training with walking

3. Spirometer

4. Peak flow meter

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX-4

Spirometry

is the most common of the pulmonary function tests (PFTs), measuring lung function, specifically the amount (volume) and speed (flow) of air that can be inhaled and exhaled.

Spirometry is an important tool used for generating graphs, which are helpful in assessing conditions such as asthma, pulmonary fibrosis, cystic fibrosis, and COPD.

The spirometry test is performed using a device called a spirometer, which comes in several different varieties. Mostly spirometer display the following graph called spirograms.

Procedure

The basic forced volume vital capacity (FVC) test varies slightly depending on the equipment used.

Generally, the patient is asked to take the deepest breath they can, and then exhale into the sensor as hard as possible, for as long as possible, preferably at least 6 seconds. It is sometimes directly followed by a rapid inhalation (inspiration), in particular when assessing possible upper airway obstruction. Sometimes, the test will be preceded by a period of quiet breathing in and out from the sensor (tidal volume), or the rapid breath in (forced inspiratory part) will come before the forced exhalation.

During the test, soft nose clips may be used to prevent air escaping through the nose. Filter mouthpieces may be used to prevent the spread of microorganisms.

Peakflowmeter

The peak expiratory flow (PEF), also called peak expiratory flow rate (PEFR) is a person's maximum speed of expiration, as measured with a peak flow meter, a small, hand-held device used to monitor a person's ability to breathe out air. It measures the airflow through the bronchi and thus the degree of obstruction in the airways.

Bruce Protocol

is a maximal exercise test where the athlete works to complete exhaustion as the treadmill speed and incline is increased every three minutes.

The Bruce treadmill test protocol was designed in 1963 by **Robert. A. Bruce, MD**, as a non-invasive test to assess patients with suspected heart disease. In a clinical setting, the Bruce treadmill test is sometimes called a stress test or exercise tolerance test

The high intensity treadmill training is individual walking programme from **bruce protocol**.

The low intensity treadmill training is individual walking programme from **modified bruce protocol**.

HIGH INTENSITY TRAINING

After selection of 15 subjects according to the inclusion criteria, the group A is trained with maximal treadmill walking.

Phase I

WARM UP EXERCISES

- Flexion and extension with both and alternate extremity counts.

- Abduction and adduction with both and alternate extremity counts.
- slow jogging.
- Duration : 3 minutes

Phase II

Individualized walking programme in treadmill training with 4 stages of Bruce protocol.

PROTOCOL

STAGE	DURATION	SPEED	GRADE %	METS
1	3 min	1.7 MPH	10	5
2	3 min	2.5 MPH	12	7
3	3 min	3.4 MPH	14	10
4	3 min	4.2 MPH	16	13
5	3 min	5.0 MPH	18	16
6	3 min	5.5 MPH	20	19
7	3 min	6.0 MPH	22	22

Intensity of training

High intensity is given up to 80% of target heart rate.

$$\text{THR} = \text{RHR} + 80\% [\text{MAX HR} - \text{RHR}]$$

Duration of training

Warm up 3 minutes, training 12 minutes, cool down 3 minutes, the total time is 18 minutes.

Frequency of training 3 sessions/ week

Period of training 3 months

Phase III

COOLDOWN PERIOD

exercise for 3 minutes like jogging, running walking with slow intensity.

LOW INTENSITY TRAINING

After selection of 15 subjects according to the inclusion criteria, the group B is trained with treadmill walking.

Phase I

WARM UP PERIOD

- Flexion and extension with both and alternate extremity counts.
- Abduction and adduction with both and alternate extremity counts.
- Slow jogging
- Duration: 3 minutes

Phase II

Individualized walking programme in treadmill training with 4 stages of modified Bruce protocol.

PROTOCOL

STAGE	DURATION	SPEED	GRADE %	METS
1	3 min	1.7 MPH	0	1.7
2	3 min	1.7 MPH	5	2.8
3	3 min	1.7 MPH	10	5.4
4	3 min	2.5 MPH	12	7.0
5	3 min	3.4 MPH	14	10
6	3 min	4.2 MPH	16	13
7	3 min	5.0 MPH	18	17

Intensity of training

Low intensity is given up to 60% of target heart rate.

$$\text{THR} = \text{RHR} + 60\%[\text{MAX HR} - \text{RHR}]$$

Duration of training

Warm up 3 minutes, training 12 minutes, cool down 3 minutes, the total time is 18 minutes.

Frequency of training 3 sessions/week

Period of training 3 months

Phase III

COOL DOWN PERIOD

Exercises for 3 minutes like mild stretching, walking with slow intensity.

Precaution for termination of the exercise session

- Persistent dyspnea
- Dizziness
- Pain
- Severe leg claudication
- Excessive fatigue
- Ataxia
- Stable angina
- Discomfort

Check the heart rate, blood pressure during the pulmonary function test.

APPENDIX – 5

GROUP-A

S.No	Age	Sex	FVC		FEV1		PEFR	
			Pre test	Post test	Pre test	Post test	Pre test	Post test
1.	57	M	72	82	65	80	160	210
2.	57	M	74	84	66	82	165	205
3.	57	F	73	83	68	84	170	215
4.	56	M	75	85	70	80	175	215
5.	57	F	71	81	67	77	160	205
6.	57	M	73	83	69	85	175	215
7.	56	M	75	85	69	85	165	205
8.	57	F	74	84	67	77	155	205
9.	57	F	72	84	70	80	160	205
10.	57	F	71	82	65	76	165	210
11.	56	M	72	82	66	82	155	205
12.	57	M	70	82	67	80	175	215
13.	57	M	75	85	65	76	165	205
14.	56	M	73	83	66	82	160	210
15	56	M	71	82	69	81	175	215

F- Female M-Male

GROUP-B

S.No	Age	Sex	FVC		FEV1		PEFR	
			Pre test	Post test	Pre test	Post test	Pre test	Post test
1.	56	M	65	75	69	79	175	190
2.	56	M	66	76	66	76	160	195
3.	55	M	70	77	65	75	165	190
4.	56	F	64	78	66	76	155	195
5.	56	F	67	77	67	77	165	195
6.	55	M	64	76	69	79	175	200
7.	56	F	70	78	70	80	170	195
8.	55	M	65	75	70	78	160	200
9.	55	M	67	77	69	79	165	195
10.	56	F	64	78	65	75	170	195
11.	56	F	65	76	66	76	155	195
12.	56	F	64	77	65	75	160	200
13.	55	M	70	78	69	79	165	200
14.	55	M	64	76	70	78	165	200
15.	56	M	67	77	68	78	160	200

F- Female M-Male

CHAPTER-1

"INTRODUCTION."

CHAPTER-2

"*REVIEW OF LITERATURE*."

CHAPTER-3

*"MATERIALS AND
METHODOLOGY."*

CHAPTER-4

**"DATA PRESENTATION AND
ANALYSIS."**

CHAPTER-5

"RESULTS AND DISCUSSION."

CHAPTER-6

"SUMMARY AND CONCLUSION."

"BIBLIOGRAPHY"

" APPENDICES "